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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.			SOROUSH, ALI	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,911	Applicant(s) KAMAGUCHI ET AL.	
	Examiner ALI SOROUGH	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 09/04/2009 to the Office Action mailed on 06/05/2009 is acknowledged.

Status of the Claims

Claims 1, 2, 4, 5, 6, and 9 are currently amended and claim 3 is cancelled. Therefore, claims 1, 2, and 4-10 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.

Art Unit: 1616

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. The rejection of claims 1 and 2 under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al. (US Patent 5330835, 07/19/1994) in view of Yamamoto et al. (US Patent 5431917, Published 07/11/1995) **is maintained.**

Applicant Claims

Applicant claims a heat resistant capsule comprising a covering film and a capsule filler solution encapsulated therein, wherein covering film comprises 80% by weight or more relative to the total weight of the covering film of curdlan. Applicant further claims a process for producing a heat resistant capsule comprising simultaneously extruding a capsule filler solution, capsule covering film solution, and an oil solution through multiple nozzle composed of at least three nozzles concentrically arranged, having sequentially increasing radius. Wherein, the capsule covering film solution contains curdlan.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Kikuchi et al. teach, "A seamless capsule comprising a content and film coating said content is disclosed. The content is a hydrophilic substance." (See abstract). " A capsule content 4 which is supplied into a nozzle part is extruded from an inner nozzle (first nozzle) 1 and a viscous liquid which is scarcely miscible with water is extruded from an annular pore tip of an intermediate nozzle (second nozzle) 2 and, at the same time, a film solution for seamless capsule 6 is extruded from an annular pore tip of an

Art Unit: 1616

outer nozzle (third nozzle) 3, and then a three-phase composite jet this obtained is ejected into a cooling solution 8 to obtain a seamless capsule 7 of the present invention.

The capsule 7 comprises a central core 9, a film-forming outer wall 10 and a discrete layer 11 between the central core 9 and the outer wall 10." (See column 3, Lines 38-50).

"A seamless capsule in the following Examples is composed of a content solution (solution I), a viscous liquid (solution II) which is present between a film solution and the content solution and the film solution (solution III)." (See column 4, Lines 23-27). One exemplified formulation comprises 70% solution I: 96.5% polyethylene, 2.0% herb extract, 1.0% sweetener and 0.5% flavor, 20% solution II: 80.0% sucrose fatty acid ester, 15.0% menthol, 5.0% flavor, and 10% solution III: 20.0% gelatin (80% covering film matrix), 5.0% sorbitol and 75.0% water. (See Column 4, Example 1). "By using a concentric triplex nozzle, a herb extract solution containing PEG 400 as a solvent (solution I) was extruded from an inner nozzle and 1-menthol solution containing sucrose fatty acid ester as a main ingredient (solution II) heated to 80°C was extruded from an intermediate nozzle and, at the same time, a gelatin solution (solution III) heated to 60°C was extruded from an outer nozzle to form a three-phase jet in a ratio shown in Formulation 1, and then the jet was injected into a vegetable oil cooled to 12°C ... to obtain a seamless capsule ... The capsule was transparent and had good mouth feel and taste." (See column 4, Lines 54-68).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Kikuchi et al. lacks a teaching wherein the film solution comprises curdlan. This deficiency is cured by the teachings of Yamamoto et al.

Yamamoto et al. teach, "A method of producing a hard capsule for pharmaceutical drugs, comprising: preparing an aqueous solution of a capsule base containing a water soluble cellulose derivative ... a gelatinizing agent and an auxiliary for gelation ..." (See column 7, claim 1). "The method for producing a hard capsule according to claim 1, wherein the gelatinizing agent is selected from the group consisting of ... curdlan, gelatin ..." (See column 8, claim 11).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one skilled in the art at the time of the instant invention to combine the teachings of Kikuchi et al. with Yamamoto et al. One would have motivated to substitute curdlan for the gelatin in the film solution taught by Kikuchi et al. since gelatin is an animal product which can be contaminated with BSE and curdlan is a safer suitable alternative to gelatin. For the foregoing reasons, the instantly claimed composition would have been suggested to one of ordinary skill in the art.

Response to Applicant's Arguments

Applicant argues that neither Kikuchi et al. nor Yamamoto et al. teach a shell composition comprising 80% curdlan. Applicant's argument has been fully considered but found not to be persuasive. It is the Examiners position that one of ordinary skill in the art would have arrived at the instant concentration through routine optimization. One would have been motivated to adjust the amount of curdlan based on the amount of

Art Unit: 1616

gelling one needed for the capsules. For the foregoing reasons, the rejection of claims 1 and 2 under 102(b) is maintained.

New Grounds of Rejection

1. Claims 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al. (US Patent 5330835, 07/19/1994) in view of Kiefer et al. (US Patent 6174466 B1, Published 01/16/2001) further in view of Kamaguchi et al. (International Application Published Under the PCT WO 03/043609, Published 05/30/2003 or US Patent 7255921 B2 the English Equivalent).

Applicant Claims

Applicant claims a process for producing a heat resistant capsule comprising simultaneously extruding a capsule filler solution, capsule covering film solution, and an oil solution through multiple nozzle composed of at least three nozzles concentrically arranged, having sequentially increasing radius. Wherein, the capsule covering film solution contains curdlan.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Kikuchi et al. teach, "A seamless capsule comprising a content and film coating said content is disclosed. The content is a hydrophilic substance." (See abstract). " A capsule content 4 which is supplied into a nozzle part is extruded from an inner nozzle (first nozzle) 1 and a viscous liquid which is scarcely miscible with water is extruded from an annular pore tip of an intermediate nozzle (second nozzle) 2 and, at the same

Art Unit: 1616

time, a film solution for seamless capsule 6 is extruded from an annular pore tip of an outer nozzle (third nozzle) 3, and then a three-phase composite jet this obtained is ejected into a cooling solution 8 to obtain a seamless capsule 7 of the present invention.

The capsule 7 comprises a central core 9, a film-forming outer wall 10 and a discrete layer 11 between the central core 9 and the outer wall 10." (See column 3, Lines 38-50).

"A seamless capsule in the following Examples is composed of a content solution (solution I), a viscous liquid (solution II) which is present between a film solution and the content solution and the film solution (solution III)." (See column 4, Lines 23-27). One exemplified formulation comprises 70% solution I: 96.5% polyethylene, 2.0% herb extract, 1.0% sweetener and 0.5% flavor, 20% solution II: 80.0% sucrose fatty acid ester, 15.0% menthol, 5.0% flavor, and 10% solution III: 20.0% gelatin (80% covering film matrix), 5.0% sorbitol and 75.0% water. (See Column 4, Example 1). "By using a concentric triplex nozzle, a herb extract solution containing PEG 400 as a solvent (solution I) was extruded from an inner nozzle and 1-menthol solution containing sucrose fatty acid ester as a main ingredient (solution II) heated to 80°C was extruded from an intermediate nozzle and, at the same time, a gelatin solution (solution III) heated to 60°C was extruded from an outer nozzle to form a three-phase jet in a ratio shown in Formulation 1, and then the jet was injected into a vegetable oil cooled to 12°C ... to obtain a seamless capsule ... The capsule was transparent and had good mouth feel and taste." (See column 4, Lines 54-68).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Kikuchi et al. lacks a teaching wherein the film solution comprises curdlan. This deficiency is cured by the teachings of Kamaguchi et al.

Kamaguchi et al. teach, "Particularly, the present invention provides a non-gelatinous capsule shell composition comprising a starch hydrolyzate as a base and a gelling agent." (See column 2, Lines 28-30). "As a gelling agent, polysaccharides from plant, which melts at a temperature not more than 80°C, are suitably used, and examples thereof include one or combination of two or more selected from the group consisting of ... curdlan ..." (See column 4, Lines 14-18). "The gelling agent is contained in an amount of 0.5 to 30% by weight, preferably 1 to 15% by weight, based on total weight of the solid content in the capsule shell composition. (See column 4, Lines 29-31). Optionally, a shell reinforcer may be used including polysaccharides such as pullulan, gum arabic, arabinogalactan, cellulose and derivatives thereof. (See column 4, Lines 44-55). "The capsule of the present invention may be a seamless capsule. The capsule can be produced by a method of continuously producing seamless capsule by a dripping process using a multiple nozzle ... In the dripping process using a multiple nozzle, after concentric multiple nozzle, which is doublet or more, is inserted into liquid oil flowing down at a constant rate, the content substance is ejected through an innermost nozzle and the non-gelatinous capsule shell composition is ejected through an outermost nozzle, simultaneously, at a constant rate to continuously produce spherical seamless capsule by interfacial tension applied between the liquid oil and shell substance." (See column 5, Lines 45-59). "[G]elatin is animal protein from livestock ... it is difficult to contain a substance that reacts with a protein as

Art Unit: 1616

a capsule content therein. It is a problem that the gelatin shell is easily insoluble or brittle with time and the heat resistance thereof is degraded when the moisture is increased. There have been cases that gelatin is incepted to have an allergy thereto and is restricted to use religiously or from vegetarianism. In addition, recently, it has been difficult to use gelatin for the reason of infection or contamination of livestock diseases, such as mad cow disease (BSE), foot and out disease to human. Therefore, it has been required to develop non-gelatinous capsule shell without using gelatin as a base." (See column 1, Lines 17-30).

Kikuchi et al. lacks a teaching wherein the composite jet is extruded into a heated oil solution of 80C or more. This deficiency is cured by the teachings of Kiefer et al.

Kiefer et al. teach a method for making seamless capsules. (See title). "The shell material and the core material were simultaneously extruded from the outer and inner nozzles, respectively ... into heated coconut oil ... maintained at 100C." (See column 12, Lines 25-35). "In accordance with the present invention there is provided a method and apparatus for cooling the seamless capsules without the need for an excessively long, cooling duct." (See column 4, Lines 28-31). "Because the heated ... liquid is at the temperature that is close to the shell material coaxial jet, it prevents the shell material from solidifying, thereby allowing the shell material to encapsulate the core material to form capsules." (See column 9, Line 67 and column 10, Lines 1-4).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

Art Unit: 1616

It would have been obvious to one of ordinary skill at the time of the instant invention to combine the teachings of Kikuchi et al. with Kamaguchi et al. One would have motivated to do so because the combination would provide a non-gelatinous seamless capsule shell able to retain a hydrophilic substance.

It would have been obvious to one of ordinary skill at the time of the instant invention to combine the teachings of Kikuchi et al. with Kiefer et al. One would have been motivated to do so in order to extrude the jet composite into a heated oil and then followed by a cooling oil in order to ensure the encapsulation of the core material and reducing the need for an excessively long cooling duct.

With regard to instant claim 5 limitation of a fourth nozzle extruding a liquid substance for isolating the capsule filler solution and capsule film, it is the Examiners position that this is made obvious by the teachings of Kikuchi et al. One of ordinary skill at the time of the instant invention would have been motivated to add a fourth nozzle that extrudes and isolating liquid substance, since Kikuchi et al. teach that the multiple nozzle may have more than three concentrically arranged nozzles and further that solution for isolating the capsule solution from the capsule film in order to reduce content of the hydrophilic substance transferring to the film to soften the capsule. For the foregoing reasons, the instantly claimed composition would have been suggested to one of ordinary skill in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1616

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

Art Unit: 1616

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/

Primary Examiner, Art Unit 1616